

REMARKS

Claims 22-42 are now present in this application. Claims 22, 41 and 42 are independent. By this Amendment, claims 22, 40 and 41 are amended, and claim 42 is added. No new matter is involved. Support for the claimed amendments is found, for example, in Fig. 26 and the portions of the disclosure that describe Fig. 26.

Reconsideration of this application, as amended, is respectfully requested.

CONTINUED ELECTION WITH TRAVERSE

Applicants respectfully continue to submit that the outstanding Office Action is unclear and fails to respond to the merits of Applicants' election of species filed on July 30, 2008, as required by MPEP §707.07(f).

In the Election filed on July 30, 2008, Applicants elected, with traverse, species 4-9, Figs. 19-26, with traverse, and set forth four full paragraphs of reasons why the election of species requirement was improper.

Instead of responding to those four paragraphs, the outstanding Office Action totally ignores them, thereby denying Applicants substantive and procedural due process under the Administrative Procedures Act, as explained in *In re Zurko*, 119 S.Ct. 1816, 50 USPQ2d 1930 (1999), and *In re Gartside*, 53 USPQ2d 1769 (Fed. Cir. 2000), as well as MPEP §707.07(a), and is direct violation of the requirement to address Applicants' reasons for traversing the requirement on the merits in MPEP §707.07(f). For this reason alone, the election of species requirements of record in this Application are fundamentally improper and should be withdrawn.

The fundamentally improper outstanding election of species requirement focuses on subspecies of the elected species, and makes a further election of species requirement.

However, this outstanding sub-species election requirement is as improper as the original election of species requirement, for a number of reasons.

Firstly, the claimed invention recites combinations and subcombinations, and it is fundamentally improper to limit examination of this Application to species and subspecies of elements recited in the claimed combinations and combinations of those elements.

In this regard, an Applicant is free to define his or her invention, and cannot be told what to claim by the USPTO, or any Examiner in the USPTO. See *In re Borkowski*, 164 USPQ 642, 645 (CCPA 1970), where the court stated that “[W]hile the examiner states the requirement to be claims which “particularly point out and distinctly claim *the invention* “(emphasis added), § 112 actually requires claims “particularly pointing out and distinctly claiming *the subject matter which applicant regards as his invention* “(emphasis added). In reality, this means that applicant must particularly point out and distinctly claim the “*subject matter sought to be patented*”.

In other words, as explained in the “Borkowski” decision, an Applicant is free to define what he or she regards as the invention, and it is improper for an Examiner to tell the Applicant how to claim what the Applicant regards as his invention.

In this Application Applicants present two independent claims.

Independent claim 41, for example, recites a dorsolumbar and lumbosacral vertebral fixation system which comprises: (1) at least one connector or coupling; (2) a rod; and (3) a device for vertebral fixation.

This is a combination invention claim. Independent claim 22 is also a combination claim, which also recites at least one connector or coupling, a rod and a device for vertebral fixation.

All other claims depend from either one of these combination invention claims and, as such, are also combination invention claims.

The Examiner has to examine the claimed invention, and cannot redefine the invention, as has been done here, so that the Examiner can limit what has to be searched and examined. In the prosecution of this Application, the Examiner has improperly ignored the claimed combination invention, and has chosen to try to limit examination to what is not claimed.

Applicants have not claimed pedicle hooks, *per se*, and have not claimed swivels, *per se*, but have claimed the aforementioned combinations and if the Examiner wants to restrict between independent and distinct inventions, any restriction requirement must be based on the claimed invention, which is a combination invention, and not element of the claimed combination invention such as, for example, some hook invention, *per se*, or swivel invention, *per se*.

The first Office Action, dated May 30, 2008, in which the Examiner indicated that the claims are directed to nine patentably distinct species, had a similar problem.

In the May 30, 2009 Office Action, the first allegedly patentably distinct species was Fig. 1, which is a screw. Unfortunately, the claimed invention does not recite a screw, but recites the combination of (1) at least one connector or coupling; (2) a rod; and (3) a device for vertebral fixation. Thus, Fig. 1 is only an element of what is recited in each independent claim.

The second allegedly patentably distinct species is Fig. 10, which is an exploded perspective view of a clamp and a rod, is not the combination invention recited in either independent claim. Rather it is just an element of what is recited in each independent claim.

The third allegedly patentably distinct species is Fig. 15, which is a clamp embodiment, and is not the combination recited in each independent claim. Rather, it is just an element of what is recited in each independent claim.

The fourth allegedly patentably distinct species is Fig. 19, which is a cross-section of an expansion screw, and is not the combination recited in each independent claim. Rather, it is just an element of what is recited in each independent claim.

The fifth, sixth, seventh, eighth and ninth allegedly patentably distinct species are Figs. 20, 21, 22, 23 and 24, respectively, none of which is the combination recited in each independent claim. Fig. 20 is just a rod (element); Fig. 21 shows a clamp, which is an element of, not the combination recited in, the independent claims; Fig. 22 shows a hook, which is an element of, not the combination recited in, the independent claims; Fig. 23 is a swivel, which is an element of, not the combination recited in, the independent claims; and Fig. 24 is another hook, which is an element of, not the combination recited in, the independent claims.

Instead of making a restriction requirement directed to the claimed invention, the Examiner improperly made an election of species requirement that was not directed to the claimed invention, but was, instead, directed to something that was not claimed, and was directed not to claimed species invention, but was directed to different claimed combination inventions, none of which was a proper species of a generic invention.

Additionally, for any restriction requirement (including an election of species requirement) to be proper, the Office has to demonstrate that there is no serious search burden on the Examiner. In this regard, the Office Action has not even addressed this requirement, let alone demonstrated that there is any serious administrative burden on the Examiner to examine

all pending claims, i.e., claims 22-41. MPEP §803 makes it clear that for a restriction to be proper, the Examiner must show that (1) the claims are independent and distinct, and (2) there would be a serious burden on the Examiner if restriction is not required.

An Examiner cannot overcome this requirement, explicitly set forth in MPEP §803 (that even if the application contains independent and distinct invention, if the search and examination of the entire application can be made without serious burden, the Examiner must examine it on the merits) merely by not discussing it, as is the case with both the outstanding election of species requirement and the previous election of species requirement.

Furthermore, as discussed by Applicants in the previous election of species response, there are only two independent claims, and the remaining claims are dependent claims which necessarily contain all of the features of the independent claim from which they depend, one result of which is that the dependent claims are not mutually exclusive from the independent claims and, for this additional reason, all claims must be examined on their merits with respect to the elected species.

Applicants also respectfully submit that this position is fully supported by the decision of the Court of Customs and Patent Appeals in, In re Muller, 163 USPQ 641 (CCPA 1969), which states that “. . . it should be noted that the addition of a limitation to a claim, as distinguished from the substitution of a limitation, can never result in a claim to a different species.”

For the reasons set forth above, Applicants respectfully submit that the elections of species requirements of record are fundamentally improper and should be withdrawn, and that all pending claims should be examined on their merits in the next Office Action.

In reply to the Office Action's responses, found in section 1, bridging pages 2 and 3 of the office Action, Applicants respectfully note that Applicants have not admitted that the claims are mutually exclusive. As pointed out above, and in Applicants' previous reply to the restriction/election requirement, as discussed by Applicants in the previous election of species response, there are only two independent claims, and the remaining claims are dependent claims which necessarily contain all of the features of the independent claim from which they depend, one result of which is that the dependent claims are not mutually exclusive from the independent claims and, for this additional reason, all claims must be examined on their merits with respect to the elected species.

Additionally, Applicants also respectfully submit that this position is fully supported by the decision of the Court of Customs and Patent Appeals in, In re Muller, 163 USPQ 64'1 (CCPA 1969), which states that "... it should be noted that the addition of a limitation to a claim, as distinguished from the substitution of a limitation, can never result in a claim to a different species."

The Office Action's responsive arguments directed to Applicants' "mutually exclusive" arguments improperly continue to ignore the claimed invention.

The Office Action continues to focus not on the claimed invention, but what the examiner describes as different species. However, Applicants have made an election of species, with traverse, and the claims read on the elected species – which the Office Action does not address or otherwise come to grips with.

With respect to the statements found in section 2 on pages 3 through 5, applicants note that the Office Action continues not to address the claimed invention. Moreover, the statements

in the last two paragraphs on page 5 of the outstanding Office Action improperly try to coerce Applicants to drop their traversal of the restriction/election of species requirements because “the prosecution of the application will be lengthened forever” and “is completely counterproductive to both Applicant and the Office” and “when the prosecution of this Application takes too much more time than time allowed by the Office, the examiner will fail to meet the production goal pre-determined by the Office and face severe disciplinary action including termination.”

It appears that the Examiner is saying that if Applicants have the temerity to choose to avail themselves of their rights to prosecute this Application according to the U.S. patent statutes and Rules of Practice and MPEP, they will get the Examiner terminated.

Applicants respectfully submit that this line of reasoning is extremely prejudicial to Applicants’ rights to prosecute this Application according to the requirements of the Administrative Procedures Act, which the USPTO has to follow, and is improper to raise in the prosecution of this application, and that these arguments should be expunged from the record.

RENEWED CONTINGENT PETITION UNDER 37 CFR §§1.181 AND 1.244

Applicants respectfully renew their previously filed Contingent Petition to the Commissioner and ask that it be decided promptly because that contingency has occurred. In this regard, Applicants note that the Examiner denied Applicants’ request for reconsideration of the election of species requirements filed on April 8, 2009.

Accordingly, Applicants respectfully request that the Commissioner or Director exercise supervisory authority over the Examiner and require that the election of species requirements of

record be withdrawn and that all pending claims be examined on their merits, for the reasons presented above.

Rejections under 35 USC §102

Claims 22, 38, 30 and 41 stand rejected under 35 USC §102(b) as being anticipated by U.S. Patent 5,562,662 to Brumfield. These rejections are respectfully traversed.

A prior art reference anticipates the subject matter of a claim when that reference discloses every feature of the claimed invention, either explicitly or inherently. *In re Schreiber*, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431 (Fed. Cir. 1997) and *Hazani v. Int'l Trade Comm'n*, 126 F.3d 1473, 1477, 44 USPQ2d 1358, 1361 (Fed Cir. 1997). While, of course, it is possible that it is inherent in the operation of the prior art device that a particular element operates as theorized by the Examiner, inherency may not be established by probabilities or possibilities. What is *inherent*, must necessarily be disclosed. *See In re Oelrich*, 666 F.2d 578, 581, 212 USPQ 323, 326 (CCPA 1981); *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993).

During patent examination the PTO bears the initial burden of presenting a *prima facie* case of unpatentability. *See In re Oetiker*, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992); *In re Piasecki*, 745 F.2d 1468, 1472, 223 USPQ 785, 788 (Fed. Cir. 1984). If the PTO fails to meet this burden, then the applicant is entitled to the patent. However, when a *prima facie* case is made, the burden shifts to the applicant to come forward with evidence and/or argument supporting patentability. Patentability *vel non* is then determined on the entirety of the

record, by a preponderance of evidence and weight of argument, *In re Gulag*, 62 USPQ2d 1151 (Fed. Cir. 2002).

Moreover, as stated in MPEP §707.07(d), where a claim is refused for any reason relating to the merits thereof it should be "rejected" and the ground of rejection fully and clearly stated.

Additionally, findings of fact and conclusions of law by the USPTO must be made in accordance with the Administrative Procedure Act, 5 U.S.C. §706(A), (E) (1994). *See Zurko v. Dickinson*, 527 U.S. 150, 158, 119 S.Ct. 1816, 1821, 50 USPQ2d 1930, 1934 (1999).

A claim limitation is inherent in the prior art if it is necessarily present in the prior art, not merely probably or possibly present. *See Rosco v. Mirro Lite*, 304 F.3d 1373, 1380, 64 USPQ2d 1676 (Fed. Cir. 2002). The dispositive question regarding anticipation is whether one skilled in the art would reasonably understand or infer from the prior reference's teaching that every claim feature or limitation was disclosed in that single reference, *Dayco Products, Inc. v. Total Containment, Inc.*, 329 F.3d 1358, 1368, 66 USPQ2d 1801 (Fed. Cir. 2003).

Brumfield does not disclose the combination of features recited in independent claim 22. For example, Brumfield fails to disclose wherein the tails of the vertebral fixation elements are threadedly adapted to be screwed to the coupling or connector to the rod.

Nor does Brumfield disclose the features recited in amended independent claim 41, including wherein a tail of the device for vertebral fixation is threadedly adapted to be screwed to the at least one connector or coupling, and the at least one connector or coupling is adapted to be attached to the rod, the device for vertebral fixation is adapted to be introduced to either a pedicle or vertebral laminae, the rod is adapted to be inserted through the at least one connector or

coupling, and the at least one connector or coupling is adapted to be connected to the tail of the device for vertebral fixation.

Accordingly, claims 1, 38, 39 and 41 are not anticipated by Brumfield.

Reconsideration and withdrawal of this rejection are respectfully requested.

Rejection under 35 USC §103

Claim 40 stands rejected under 35 USC §103(a) as being unpatentable over Brumfield. This rejection is respectfully traversed.

Claim 40, as amended, depends from new claim 42. Both claims 40 and 42 positively recite a combination of features that is not rendered obvious by Brumfield. For example, as amended, claim 40 now recites that the open tail of the device for vertebral fixation is adapted to be attached to the rod and locked into place by a setscrew on the inside of the open tail and a locknut on the outside of the open tail, and the open tail hook has an opening and is adapted to receive the rod inside of its opening.

This combination of features is clearly not disclosed by Brumfield.

Accordingly, claim 40, as amended, clearly defines in a patentable manner over Brumfield.

Reconsideration and withdrawal of this rejection of claim 40 are respectfully requested.

New Claim 42

New claim 42 positively recites a combination of features that is neither disclosed nor suggested by Brumfield. For example, claim 40 recites that the open tail of the device for vertebral fixation is adapted to be attached to the rod and locked into place by a setscrew on the

inside of the open tail and a locknut on the outside of the open tail. This feature is clearly neither disclosed nor suggested by Brumfield.

Thus, consideration and allowance of claim 42 are respectfully requested.

Conclusion

All of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot, and the election/restriction requirement has been properly traversed, and should be withdrawn. Additionally, as noted above, Applicants' Contingent Petition under 37 CFR §1.181 and §1.244 should be decided promptly by the Commissioner, and the restriction/election requirement withdrawn and all claims should be acted upon their merits in the next Office Action.

Applicants also respectfully request that the Examiner reconsider all presently outstanding rejections and that they be withdrawn. It is believed that a full and complete response has been made to the outstanding Office Action, and as such, the present application is in condition for allowance.

If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone Robert J. Webster, Registration No. 46, 472, at (703) 205-8000, in the Washington, D.C. area.

Prompt and favorable consideration of this Amendment is respectfully requested.

Application No. 10/660,685
Reply to Office Action dated September 3, 2009

Docket No.: 2644-0105P

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. §§ 1.16 or 1.17; particularly, extension of time fees.

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Respectfully submitted,

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